

The National Healthcare Safety Network (NHSN) Manual

Patient Safety Component

Protocol

Multidrug-resistant Organism (MDRO) and

Clostridium difficile-Associated Disease (CDAD) Module

Division of Healthcare Quality Promotion

National Center for Preparedness, Detection and Control of Infectious Diseases

Centers for Disease Control and Prevention

Atlanta, GA USA



Table of Contents

Background Table 1. Required and Optional Reporting Choices for MDRO and CDAD Module	
I. MDRO Option	
Methodology	
A. Required Reporting	
Option 1. MDRO Infection Surveillance – (MRSA, MRSA/MSSA, VRE, <i>Klebsiella</i> spp.,	
Acinetobacter spp.)	6
Option 2. Laboratory-Identified (LabID) Event	7
B. Optional Reporting	11
Prevention Process Measures Surveillance	11
a. Monitoring Adherence to Hand Hygiene	11
b. Monitoring Adherence to Gown and Gloves Use as Part of Contact Precautions	12
c. Monitoring Adherence to Active Surveillance Testing	13
2. Active Surveillance Testing Outcome Measures	15
II. Clostridium difficile-Associated Disease (CDAD) Option	19
Methodology	19
A. Required Reporting	20
Option 1. Clostridium difficile Infection Surveillance	20
Option 2. Clostridium difficile Laboratory-identified Event	21
B. Optional Reporting	24
Prevention Process Measures Surveillance	24
Figure 1. MDRO Test Result Algorithm for Laboratory-Identified (LabID) Events	25
Figure 2. C. difficile Test Result Algorithm for Laboratory-Identified (LabID) Events	26
Table 2. Rates and Measures Derived from Various MDRO and CDI Protocol Surveillance	
Vethods	27



Background

Methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant *Enterococcus* spp. (VRE) and certain gram-negative bacilli have increased in prevalence in U.S. hospitals over the last three decades, and have important implications for patient safety. A primary reason for concern about these multidrug-resistant organisms (MDROs) is that options for treating patients with these infections are often extremely limited, and MDRO infections are associated with increased lengths of stay, costs, and mortality. Many of these traits have also been observed for *Clostridium difficile*-associated disease (CDAD). Recently, the Division of Healthcare Quality Promotion (DHQP) and the Healthcare Infection Control Practices Advisory Committee (HICPAC) approved guidelines for the control of MDROs. These are available at (http://www.cdc.gov/ncidod/dhqp/pdf/ar/mdroGuideline2006.pdf). The MDRO and CDAD module of the NHSN can provide a tool to assist facilities in meeting some of the criteria outlined in the guidelines. In addition, many of the metrics used in this module are consistent with "Recommendations for Metrics for Multidrug-Resistant Organisms in Healthcare Settings: SHEA/HICPAC Position Paper" [Cohen, et al. *Infection Control and Hospital Epidemiology*. Oct 2008;29:901-913].

Clostridium difficile is responsible for a spectrum of *C. difficile* infections (CDI) [originally referred to as *C. difficile*-associated disease or CDAD], including uncomplicated diarrhea, pseudomembranous colitis, and toxic megacolon which can, in some instances, lead to sepsis and even death. Current CDC definitions for healthcare-associated infections, while adequate for the site of infection, do not take into account the special characteristics of disease caused by *C. difficile*. Although CDI represents a subset of gastroenteritis and gastrointestinal tract infections, specific standard definitions for CDI (McDonald, et al. *Infect Control Hosp Epidemiol* 2007; 28:140-145) should be incorporated to obtain a more complete understanding of how *C. difficile* is being transmitted in a healthcare facility. Please note that the term CDI is replacing CDAD. Both terms represent the same illness and are used interchangeably as we transition this module to the newer terminology.

As outlined in this guidance, these pathogens may require specialized monitoring to evaluate if intensified infection control efforts are required to reduce the occurrence of these organisms and related infections. The goal of this module is to provide a mechanism for facilities to report and analyze these data that will inform infection control staff of the impact of targeted prevention efforts. This module contains two options, one focused on MDROs and the second on CDAD or CDI. Reporting options are summarized in Table 1.



Table 1. Required and Optional Reporting Choices for MDRO and CDAD Module

Reporting Choices	MRSA or MRSA/MSSA	VRE	<i>Klebsiella</i> spp.	Acinetobacter spp.	C. difficile
Required	Method	Method	Method	Method	Method
Infection Surveillance (*Location Specific for ≥ 3 months) Choose ≥ 1 organism	A, B	A, B	A, B	A, B	[±] A, B
OR					
Proxy Infection Measures §Laboratory-Identified (LabID) Event (*Location Specific for ≥ 3	A, B, C	A, B, C	B,C	B,C	A, B, C
<u>consecutive</u> months) Choose ≥ 1 organism					
Optional	Method	Method	Method	Method	Method
Prevention Process Measures Options: Hand Hygiene					
Adherence Gown and Gloves Use	В	В	В	В	В
Adherence Active Surveillance	В	В	В	В	В
Testing (AST) Adherence	В	В	N/A	N/A	N/A
AST Outcome Measures Incident and Prevalent Cases using AST	В	В	N/A	N/A	N/A

^{*}Location: Patient care area selected for monitoring and reported in Monthly Reporting Plan. N/A – not available or contraindicated

<u>Method</u> (minimum requirement is 3 months for Infection Surveillance or 3 consecutive months for LabID Event reporting using one of the methods below):

[±]No surveillance for CDI will be performed in Neonatal Intensive Care Units (NICU). When performing surveillance Overall facility-wide, exclude NICU patient days and admissions from totals.

[§] LabID Events can be reported Overall facility-wide, in addition to Facility-wide by location or by Selected locations.

A – Facility-wide by location. Requires the most effort but provides the most detail for local and national statistical data.

B – Selected locations within the facility (1 or more). Acceptable method, ideal for use during targeted prevention programs.

C – Overall facility-wide. Acceptable method, ideal for CDI or MDRO infrequently encountered, or smaller hospitals.



I. MDRO Option

Methodology

Facilities may choose to monitor one or more of the following MDROs: MRSA, MRSA and MSSA, VRE, multidrug-resistant *Klebsiella* spp., and multidrug-resistant *Acinetobacter* spp. (See definitions in Section IA). For *S. aureus*, both the resistant (MRSA) and the susceptible (MSSA) phenotypes can be tracked to provide concurrent measures of the susceptible pathogens as a comparison to those of the resistant pathogens in a setting of active prevention efforts targeted at the resistant pathogen.

There are 2 options for required reporting and 2 additional optional monitoring methods (See protocol Table 1):

Required Reporting Options:

- 1) MDRO infection surveillance, i.e., for each patient care area selected, surveillance for all NHSN-defined healthcare-associated infections caused by at least one MDRO.
- 2) Reporting of proxy infection measures of MDRO healthcare acquisition, exposure burden, and infection burden by using primarily laboratory data. Laboratory testing results can be used without clinical evaluation of the patient, allowing for a much less labor-intensive means to track MDROs. These can be monitored facility-wide (Method C) or for specific locations (Method A or B with unique denominator data), allowing for both location-specific and facility-wide measures.

Additional Optional Monitoring Methods:

- 3) Prevention process measures that allow facilities to systematically collect data on hand hygiene and gown and gloves use adherence, and for those conducting active surveillance testing (AST), adherence to obtaining AST.
- 4) AST outcome measures that can be reported if AST is performed, providing incidence and prevalence rates for selected MDROs.

The data collections in the MDRO Option will enable participating facilities and CDC to calculate several measures, depending on which reporting methods the facility chooses to follow (protocol Table 2 at the back of this document). NHSN forms should be used to collect all required data, using the definitions of each data field as outlined in this protocol and in the "Instructions for Completion of MDRO/CDAD Forms". When denominator data are available from electronic databases, these sources may be used as long as the counts are not substantially different (+ or -5%) from manually collected counts.

Active, patient-based, prospective surveillance of the chosen MDRO infections by a trained infection preventionist (IP) is required for MDRO infection surveillance. This means that the IP shall seek to confirm and classify infections caused by the MDRO(s) chosen for monitoring during a patient's stay in at



least one patient care location during the surveillance period. Some process measures require direct observation as described in Section IB. Personnel other than the IP may be trained to perform these observations and collect the required data elements.

A. Required Reporting

Option 1. MDRO Infection Surveillance – (MRSA, MRSA/MSSA, VRE, *Klebsiella* spp., *Acinetobacter* spp).

<u>Settings:</u> Surveillance will occur in any of 4 types of inpatient locations: (1) intensive care units (ICU), (2) specialty care areas (includes hematology/oncology wards, bone marrow transplant units, inpatient dialysis units, solid organ transplant units, long term acute care areas), (3) neonatal intensive care units (NICU), and (4) any other inpatient care location in the institution (e.g., surgical wards).

<u>Requirements:</u> Surveillance for all types of NHSN-defined healthcare-associated infections (HAIs) of the MDRO selected for monitoring in at least one location in the healthcare facility for at least <u>3 months</u> in a calendar year as indicated in the *Patient Safety Monthly Reporting Plan* (CDC 57.106).

<u>Definitions:</u> MDROs included in this module are defined below. Refer to the Device-Associated Module and Procedure-Associated Module sections of the Patient Safety Component Protocol for definitions of bloodstream infection, pneumonia, urinary tract infection, and surgical site infection. Refer to the CDC Definitions for Nosocomial Infections document for all other infection site criteria (http://www.cdc.gov/ncidod/dhqp/pdf/NNIS/NosInfDefinitions.pdf). Refer to the NHSN Key Terms section of the Patient Safety Component Protocol for assistance with variable definitions.

MDROs Defined for Infection Surveillance:

MRSA: Includes S. aureus cultured from any specimen that tests oxacillin-resistant by standard susceptibility testing methods, or by a positive result from molecular testing for mecA and PBP2a; these methods may also include positive results of specimens tested by any other FDA approved PCR test for MRSA.

MSSA: S. aureus cultured from any specimen testing as oxacillin-intermediate or -susceptible by standard susceptibility testing methods, or by a negative result from molecular testing for mecA and PBP2a.



VRE: Any Enterococcus spp. (regardless of whether identified to the species level), that is resistant to vancomycin.

MDR-Klebsiella: Klebsiella spp. testing non-susceptible (i.e., resistant or intermediate) to ceftazidime or ceftriaxone.

MDR-Acinetobacter: Acinetobacter spp. testing resistant to all agents (for which testing was done) in at least 3 antimicrobial classes including β-lactams, aminoglycosides, carbapenems, and fluoroquinolones.

β-lactams	Aminoglycosides	Carbapenems	Fluoroquinolones
Ampicillin/sulbactam Piperacillin/tazobactam Cefepime Ceftazidime	Amikacin Gentamicin Tobramycin	Imipenem Meropenem	Ciprofloxacin Levofloxacin

Numerator and Denominator Data:

Numerator: Number of infections, by MDRO type. Infections are reported on the appropriate NHSN forms: *Primary Bloodstream Infection, Pneumonia, Urinary Tract Infection, Surgical Site Infection, or MDRO or CDAD Infection Event.*

Denominator. Number of patient days. Patient Days are reported using the MDRO and CDAD Prevention Process and Outcome Measures Monthly Monitoring form (CDC 57.127). (See Instruction Table 3 for completion instructions.)

<u>Data Analysis:</u> Data are stratified by time (e.g., month, quarter, etc.) and patient care location.

MDRO Infection Incidence Rate = Number of infections by MDRO type/ Number of patient days X 1000

Option 2. Laboratory-Identified (LabID) Event

<u>Introduction:</u> To calculate proxy measures of MDRO infections, exposures, and healthcare acquisition facilities may choose to monitor laboratory-identified MDRO events. This method allows the facility to rely almost exclusively on easily obtained data from the clinical microbiology laboratory. However, some data elements, such as date admitted to the patient care location and facility may require other data sources.

Laboratory and admission data elements can be used to calculate four distinct proxy measures including: admission prevalence rate and overall prevalence rate based on clinical testing (measures of exposure burden), MDRO bloodstream infection incidence rate (measure of infection burden), and overall MDRO infection/colonization incidence rate (measure of healthcare acquisition). MDRO positive laboratory results can be reported for one or more than one organism. For *S. aureus*, both the resistant (MRSA) and



the susceptible (MSSA) phenotypes can be tracked to provide concurrent measures of the susceptible pathogens as a comparison to those of the resistant pathogens in a setting of active prevention efforts targeted at the resistant pathogen.

<u>Settings:</u> Surveillance can occur in any location: inpatient or outpatient (except outpatient dialysis centers). <u>Requirements</u>: Facilities choose at least 1 of 3 reporting methods: (A) Facility-wide by location: report location-specific data for the entire facility, requiring separate denominator submissions for each location; (B) Selected locations: report location-specific data for only selected locations; and (C) Overall facility-wide: report only one denominator for the entire facility (See protocol Table 1). Facilities must indicate each reporting choice chosen for the calendar month as indicated in the *Patient Safety Monthly Reporting Plan* (CDC 57.106). Facilities can report using Methods A & C, B & C, or A, B, or C (but not A & B). Surveillance for positive laboratory results must be reported for <u>3 consecutive months</u> to provide meaningful measures.

For each MDRO being monitored, all MDRO test results are evaluated using the algorithm in Figure 1 to determine reportable LabID events for each calendar month, <u>for each facility location</u> as determined by the reporting method chosen. All first MDRO isolates (chronologically) per month are reported as a LabID event for each unique patient regardless of specimen source (excludes tests related to active surveillance testing); if a duplicate MDRO isolate is from blood, it is reported as a LabID event only if it represents a unique blood source (i.e., no prior isolation of the MDRO in blood from the same patient in ≤ 2 weeks, even across calendar months) (Figure 1). As a general rule, at a maximum, there should be no more than 2 blood isolates (which would be very rare) reported and 1 first MDRO isolate reported on any patient during a calendar month for each location chosen for reporting. Report a single LabID Event per form.

Definitions:

MDRO Isolate: Any specimen obtained for <u>clinical decision making</u> testing positive for a MDRO (as defined above). (Excludes tests related to active surveillance testing for *S. aureus* or MRSA)

Duplicate MDRO Isolate: Any MDRO isolate from the same patient after an initial isolation of the specific MDRO during a calendar month, regardless of specimen source except unique blood source (Figure 1).

Laboratory-Identified (LabID) Event: All non-duplicate MDRO isolates from any specimen, regardless of specimen source (excludes tests related to active surveillance testing for *S. aureus* or MRSA); and unique blood source MDRO isolates.



MSSA: S. aureus cultured from any specimen testing as oxacillin-intermediate or -susceptible by standard susceptibility testing methods, or by a negative result from molecular testing for mecA and PBP2a.

<u>Unique</u> Blood Source: A MDRO isolate from blood in a patient with no prior positive blood culture for the same MDRO in \leq 2 weeks, even across calendar months (Figure 1).

Numerator and Denominator Data:

Numerator. Data will be reported using the *Laboratory-identified MDRO or CDAD Event* form (CDC 57.128) (See Instruction Table 1 for completion instructions).

Denominator. Patient days, admissions, and encounters (for ER and outpatient locations) are reported using the MDRO and CDAD Prevention Process and Outcome Measures Monthly Monitoring form (CDC 57.127). (See Instruction Table 3 for completion instructions).

Data Analysis:

Based on data provided on the LabID Event form, each event can be categorized by NHSN to populate different measures. Of note, NHSN will categorize LabID Events as healthcare facility-onset vs. community-onset to ensure that all healthcare facility-onset cases have been hospitalized at least a full 48 hours. Considering: 1) variable times of day that admissions occur and 2) the absence of clinical data to confirm if cultures represent infection incubating at the time of admission, this is operationalized by classifying positive cultures obtained on day 1 (admission date), day 2, and day 3 of admission as community-onset (CO) LabID Events and positive cultures obtained on or after day 4 as healthcare facility-onset (HO) LabID Events.

Categorizing MDRO LabID Events:

The following definitions and calculations are built into the analysis capabilities of NHSN. These are some of the main metrics, but additional calculations will be available in NHSN.

<u>Categorization of Infection/Colonization Onset Based on Date Admitted to Facility and Date Specimen</u> <u>Collected</u>:

Community-Onset (CO): LabID Event specimen collected as an outpatient or an inpatient ≤ 3 days after admission to the facility (i.e., days 1, 2, or 3 of admission).

Healthcare Facility-Onset (HO): LabID Event specimen collected > 3 days after admission to the facility (i.e., on or after day 4).



Proxy Measures for MDRO Exposure Burden:

Admission Prevalence Rate = Number of 1st LabID Events per patient per month identified \leq 3 days after admission to the location or facility / Number of patient admissions to the location or facility x 100

Location Percent Admission Prevalence that is Community-Onset = Number of Admission Prevalent LabID Events to a location that are CO / Total number Admission Prevalent LabID Events x 100

Location Percent Admission Prevalence that is Healthcare Facility-Onset = Number of Admission Prevalent LabID Events to a location that are HO / Total number of Admission Prevalent LabID Events x 100

Overall Prevalence Rate = Number of 1^{st} LabID Events per patient per month regardless of time spent in location or facility / Number of patient admissions to the location or facility x 100

Proxy Measures for MDRO Bloodstream Infection:

MDRO Bloodstream Infection Admission Prevalence Rate = Number of all unique blood source LabID Events per patient per month identified \leq 3 days after admission to the location or facility / Number of patient admissions to the location or facility x 100

MDRO Bloodstream Infection Incidence \underline{or} Incidence Density Rate = Number of all unique blood source LabID Events per patient per month identified > 3 days after admission to the location or facility / Number of patient admissions to the location or facility x 100 \underline{or} Number of patient days for the location or facility x 1,000

Proxy Measures for MDRO Healthcare Acquisition:

Overall MDRO Infection/Colonization Incidence Rate = Number of 1st LabID Events per patient per month among those with no documented prior evidence of previous infection or colonization with this specific organism type and identified > 3 days after admission to the location or facility / Number of patient admissions to the location or facility x 100

Overall MDRO Infection/Colonization Incidence Density Rate = Number of 1^{st} LabID Events per patient per month among those with no documented prior evidence of previous infection or colonization with this specific organism type and identified > 3 days after admission to the location or facility / Number of patient days for the location or facility x 1,000



B. Optional Reporting

1. Prevention Process Measures Surveillance

a. Monitoring Adherence to Hand Hygiene

Introduction: This option will allow facilities to monitor adherence to hand hygiene <u>after</u> a healthcare worker (HCW) has contact with a patient or inanimate objects in the immediate vicinity of the patient. Research studies have reported data suggesting that improved after-contact hand hygiene is associated with reduced MDRO transmission. While there are multiple opportunities for hand hygiene during patient care, for the purpose of this option, only hand hygiene <u>after</u> contact with a patient or inanimate objects in the immediate vicinity of the patient will be observed and reported. (http://www.cdc.gov/handhygiene/)

<u>Settings:</u> Surveillance will occur in any location: inpatient or outpatient.

Requirements: Surveillance for adherence to hand hygiene in at least one location in the healthcare institution for at least one calendar month as indicated in the *Patient Safety Monthly Reporting Plan* (CDC 57.106). Ideally, this should be done in patient care locations also selected for MDRO Infection Surveillance or LabID Event reporting.

In participating patient care locations, perform at least 30 different unannounced observations <u>after</u> contact with patients for as many individual HCWs as possible. For example, try to observe all types of HCWs performing a variety of patient care tasks during the course of the month, not only nurses, or not only during catheter or wound care. No personal identifiers will be collected or reported.

Definitions:

Antiseptic handwash: Washing hands with water and soap or other detergents containing an antiseptic agent.

Antiseptic hand rub: Applying an antiseptic hand-rub product to all surfaces of the hands to reduce the number of microorganisms present.

Hand hygiene: A general term that applies to either: handwashing, antiseptic hand wash, antiseptic hand rub, or surgical hand antisepsis.

Handwashing: Washing hands with plain (i.e., non-antimicrobial) soap and water.

<u>Numerator and Denominator Data:</u> Hand hygiene process measure data are reported using the *MDRO* and *CDAD Prevention Process and Outcome Measures Monthly Monitoring* Form (CDC 57. 127). (See Instruction Table 3 for completion instructions.)



Hand Hygiene:

Numerator: Hand Hygiene Performed = Total number of observed contacts during which a HCW touched either the patient or inanimate objects in the immediate vicinity of the patient and appropriate hand hygiene was <u>performed</u>.

Denominator: Hand Hygiene Indicated = Total number of observed contacts during which a HCW touched either the patient or inanimate objects in the immediate vicinity of the patient and therefore, appropriate hand hygiene was <u>indicated</u>.

<u>Data Analysis</u>: Data are stratified by time (e.g., month, quarter, etc.) and patient care location.

Hand Hygiene Percent Adherence = Number of contacts for which hand hygiene was performed / Number of contacts for which hand hygiene was indicated X 100

b. Monitoring Adherence to Gown and Gloves Use as Part of Contact Precautions

Introduction: This option will allow facilities to monitor adherence to gown and gloves use when a HCW has contact with a patient or inanimate objects in the immediate vicinity of the patient, when that patient is on Transmission-based Contact Precautions. While numerous aspects of adherence to Contact Precautions could be monitored, this surveillance option is only focused on the use of gown and gloves. (http://www.cdc.gov/ncidod/dhqp/ql_isolation_contact.html)

<u>Settings:</u> Surveillance will occur in any of 4 types of inpatient locations: (1) intensive care units (ICU), (2) specialty care areas (includes hematology/oncology wards, bone marrow transplant units, inpatient dialysis units, solid organ transplant units, long term acute care areas), (3) neonatal intensive care units (NICU), and (4) any other inpatient care location in the institution (e.g., surgical wards).

Requirements: Surveillance for adherence to gown and gloves use in at least one location in the healthcare institution for at least 1 calendar month as indicated in the *Patient Safety Monthly Reporting Plan* (CDC 57.106). Ideally, this should be done in patient care locations also selected for MDRO Infection Surveillance or LabID Event reporting.

Among patients on Transmission-based Contact Precautions in participating patient care locations, perform at least 30 unannounced observations. A total of thirty different contacts must be observed monthly among HCWs of varied occupation types. For example, try to observe all types of HCWs performing a variety of patient care tasks during the course of the month, not only nurses, or not only



during catheter or wound care. Both gown and gloves must be donned prior to contact for compliance. No personal identifiers will be collected or reported.

Definitions:

Gown and gloves use: In the context of Transmission-based Contact Precautions, the donning of both a gown and gloves prior to contact with a patient or inanimate objects in the immediate vicinity of the patient. Both a gown and gloves must be donned prior to contact for compliance.

<u>Numerator and Denominator Data:</u> Gown and gloves use process measure data are reported using the *MDRO and CDAD Prevention Process and Outcome Measures Monthly Monitoring* form (CDC 57.127). (See Instruction Table 3 for completion instructions.)

Gown and Gloves Use:

Numerator: Gown and Gloves Used = Total number of observed contacts between a HCW and a patient or inanimate objects in the immediate vicinity of the patient for which gown and gloves had been donned prior to the contact.

Denominator. Gown and Gloves Indicated = Total number of observed contacts between a HCW and a patient on Transmission-based Contact Precautions or inanimate objects in the immediate vicinity of the patient and therefore, gown and gloves were indicated.

<u>Data Analysis:</u> Data are stratified by time (e.g., month, quarter, etc.) and patient care location.

Gown and Glove Use Percent Adherence = Number of contacts for which gown and gloves were used / Number of contacts for which gown and gloves were indicated X 100

c. Monitoring Adherence to Active Surveillance Testing

<u>Introduction:</u> This option will allow facilities to monitor adherence to active surveillance testing (AST) of MRSA and/or VRE, using culturing or other methods.

<u>Settings:</u> Surveillance will occur in any of 4 types of inpatient locations: (1) intensive care units (ICU), (2) specialty care areas (includes hematology/oncology wards, bone marrow transplant units, inpatient dialysis units, solid organ transplant units, long term acute care areas), (3) neonatal intensive care units (NICU), and (4) any other inpatient care location in the institution (e.g., surgical wards).



Requirements: Surveillance of AST adherence in at least one location in the healthcare facility for at least one calendar month as indicated in the *Patient Safety Monthly Reporting Plan* (CDC 57.106). A facility may choose to report AST for MRSA and/or VRE in one or multiple patient care locations, as the facility deems appropriate. Ideally, this should be done in patient care locations also selected for MDRO Infection Surveillance or LabID Event reporting. To improve standardization of applying timing rules relating to when AST specimens are obtained, classify admission specimens as those obtained on day 1 (admission date), day 2, or day 3 (i.e., \leq 3 days). Classify discharge/transfer AST specimens as those collected on or after day 4 (i.e., \geq 3 days).

Definitions:

AST Eligible Patients: Choose one of two methods for identifying patients eligible for AST:

 All = All patients in the selected patient care area regardless of history of MRSA or VRE infection or colonization.

OR

 NHx = All patients in the selected patient care area who have NO documented positive MRSA or VRE infection or colonization during the previous 12 months (as ascertained by either a facility's laboratory records or information provided by referring facilities); and no evidence of MRSA or VRE during stay in the patient care location (i.e., they are not in Contact Precautions).

Timing of AST: Choose one of two methods for reporting the timing of AST:

• Adm = Specimens for AST obtained ≤ 3 days after admission,

OR

Both = Specimens for AST obtained ≤ 3 days after admission and, for patients' stays of > 3 days, at the time of discharge/transfer. Discharge/transfer AST should include all discharges (including discharges to other wards or deaths) and can include the most recent weekly AST if performed > 3 days after admission to the patient care location. Discharge/transfer AST should not be performed on patients who tested positive on AST admission.

Numerator and Denominator Data: Use the MDRO and CDAD Prevention Process and Outcome Measures Monthly Monitoring form (CDC 57.127) to indicate: 1) AST was performed during the month for MRSA and/or VRE, 2) AST-eligible patients, and 3) the timing of AST. No personal identifiers will be collected or reported.



AST Adherence:

Numerator: For each month during which AST is performed:

Admission AST Performed = Number of patients eligible for admission AST who had a specimen obtained for testing ≤ 3 days after admission,

AND/OR

Discharge/Transfer AST Performed = For patients' stays > 3 days, the number of discharged or transferred patients eligible for AST who had a specimen obtained for testing prior to discharge, not including the admission AST.

Denominator: For each month during which AST is performed:

Admission AST Eligible = Number of patients eligible for admission AST (All or NHx),

AND/OR

Discharge/Transfer AST Eligible = Number of patients eligible for discharge/transfer AST (All or NHx) AND in the facility location > 3 days AND negative if tested on admission.

<u>Data Analysis</u>: Data are stratified by patient care location and time (e.g., month, quarter, etc.), according to AST-eligible patients monitored and the timing of AST.

Admission AST Percent Adherence = Number of patients with admission AST Performed / Number of patients admission AST eligible X 100

Discharge/transfer AST Percent Adherence = Number of patients with discharge/transfer AST performed / Number of patients discharge/transfer AST eligible X 100

2. Active Surveillance Testing Outcome Measures

<u>Introduction</u>: This option will allow facilities to monitor the prevalent and incident case rates of MRSA and/or VRE colonization or infection. This information will assist facilities in assessing the impact of intervention programs on MRSA or VRE transmission.

<u>Settings:</u> Surveillance will occur in any of 4 types of inpatient locations: (1) intensive care units (ICU), (2) specialty care areas (includes hematology/oncology wards, bone marrow transplant units, inpatient dialysis units, solid organ transplant units, long term acute care areas), (3) neonatal intensive care units (NICU), and (4) any other inpatient care location in the institution (e.g., surgical wards).



Requirements: Surveillance for prevalent and/or incident MRSA or VRE cases in at least one location in the healthcare facility for at least one calendar month as indicated in the *Patient Safety Monthly Reporting Plan* (CDC 57.106). This can be done ONLY in locations where AST adherence is being performed. A minimum AST adherence level will be required for the system to calculate prevalence and incidence. A facility may choose to report AST for MRSA and/or VRE in one or multiple patient care locations, as the facility deems appropriate. Ideally, this should be done in patient care locations also selected for MDRO Infection Surveillance or LabID Event reporting. To improve standardization of applying timing rules relating to when AST specimens are obtained, classify admission specimens as those obtained on day 1 (admission date), day 2, or day 3 (i.e., \leq 3 days). Classify discharge/transfer AST specimens as those collected on or after day 4 (i.e., > 3 days). Only the first specimen positive for MRSA or VRE from a given patient in the patient care location is counted, whether obtained for AST or as part of clinical care. If an Admission AST specimen is not collected from an eligible patient, assume the patient has no MRSA or VRE colonization.

Definitions:

AST Admission Prevalent case:

Known Positive = A patient with documentation on admission of MRSA or VRE colonization or
infection in the previous 12 months (i.e., patient is known to be colonized or infected as ascertained
by either a facility's laboratory records or information provided by referring facilities). (All MRSA or
VRE colonized patients currently in the ICU during the first month of surveillance should be
considered "Known Positive"),

OR

 Admission AST or Clinical Positive = A patient with MRSA or VRE isolated from a specimen collected for AST ≤ 3 days after admission or from clinical specimen obtained ≤ 3 days after admission (i.e., MRSA or VRE cannot be attributed to this patient care location).

AST Incident case: A patient with a stay > 3 days:

With <u>no</u> documentation on admission of MRSA or VRE colonization or infection during the previous
 12 months (as ascertained either by the facility's laboratory records or information provided by



referring facilities); including admission AST or clinical culture obtained ≤ 3 days after admission (i.e., patient without positive specimen),

AND

 With MRSA or VRE isolated from a specimen collected for AST or clinical reasons > 3 days after admission to the patient care location or at the time of discharge/transfer from the patient care location to another location in or outside the facility (including discharges to other wards or deaths).

MRSA colonization: Carriage of MRSA without evidence of infection (e.g., nasal swab test positive for MRSA, without signs or symptoms of infection).

AST Eligible Patients: Choose one of two methods for identifying patients eligible for AST:

 All = All patients in the selected patient care area regardless of history of MRSA or VRE infection or colonization,

OR

 NHx = All patients in the selected patient care area who have NO documented positive MRSA or VRE infection or colonization during the previous 12 months (as ascertained either by the facility's laboratory records or information provided by referring facilities); and no evidence of MRSA or VRE during stay in the patient care location (i.e., they are not in Contact Precautions).

Timing of AST: Choose one of two methods for reporting the timing of AST:

• Adm = Specimens for AST obtained ≤ 3 days after admission,

OR

• Both = Specimens for AST obtained ≤ 3 days after admission and, for patients' stays of > 3 days, at the time of discharge/transfer. Discharge/transfer AST should include all discharges (including discharges to other wards or deaths) and can include the most recent weekly AST if performed > 3 days after admission to the patient care location. Discharge/transfer AST should not be performed on patients who tested positive on AST admission.

Numerator and Denominator Data: Use the MDRO and CDAD Prevention Process and Outcome Measures Monthly Monitoring form (CDC 57.127) to indicate: 1) AST outcomes monitoring and adherence was performed during the month for MRSA and/or VRE, 2) AST eligible patients, and 3) the timing of AST. No personal identifiers will be collected or reported.

If only admission AST is performed, only prevalent cases of MRSA or VRE can be detected in that patient care location. If both admission and discharge/transfer AST are performed, both prevalent and



incident cases can be detected. No personal identifiers will be collected or reported.

Admission Prevalent Case:

Numerator:

Known Positive

• Admission AST or Clinical Positive = Cases ≤ 3 days after admission

Denominator: Total number of admissions

Incident Case:

Numerator: Discharge/transfer AST or Clinical Positive = Cases > 3 days after admission

Denominator: Total number of patient days

Note: For research purposes calculating patient-days at risk (i.e., excluding patient-days in which patients were known to be MRSA or VRE colonized or infected) may be a preferable denominator, but for surveillance purposes and ease of aggregating, total number of patient days is required for this module.

<u>Data Analysis</u>: Data are stratified by patient care location and time (e.g., month, quarter, etc.) according to the eligible patients monitored and timing of AST.

AST Admission Prevalence rate =

- For Eligible patients = All:
 Number of admission AST or clinical positive / Number of admissions X 100
- For Eligible patients = NHx:
 Number of admission AST or clinical positive + Number of known positive / Number of admissions X 100

AST Incidence rate = Number of discharge/transfer AST or clinical positive / Number of patient days X 1000

18



II. Clostridium difficile-Associated Disease (CDAD) Option

Methodology

The CDAD Option also allows for a choice between the 2 required reporting options and additional optional monitoring methods. As with MDRO monitoring, if a facility chooses to monitor *C. difficile* it must use either Infection Surveillance or Laboratory-identified (LabID) Event reporting. Process measure reporting is optional (but available only for hand hygiene and gown and gloves use – no AST). (See protocol Table 1)

C. difficile Infection (CDI) Surveillance, reporting on all NHSN-defined healthcare-associated CDIs from at least one patient care area, is one surveillance option for C. difficile (i.e., part of your facility's Monthly Reporting Plan). These data will enhance the ability of NHSN to aggregate national data on CDIs. This method requires active, patient-based, prospective surveillance of healthcare-associated C. difficile infections by a trained infection preventionist (IP). This means that the IP shall seek to confirm and classify infections caused by C. difficile during a patient's stay in at least one patient care location during the surveillance period.

Laboratory-identified (LabID) Events reporting is the second surveillance option and allows laboratory testing data to be used without clinical evaluation of the patient, allowing for a much less labor intensive method to track *C. difficile*. These provide proxy measures of *C. difficile* healthcare acquisition, exposure burden, and infection burden based solely on laboratory data and limited admission date data. Reporting of LabID Events for the entire facility (i.e., Overall facility-wide) can provide easily obtainable and valuable information for the facility. LabID Events can also be monitored for specific locations with unique denominator data required from each specific location (i.e., Facility-wide by location or Selected locations). This allows for both location-specific and facility-wide measures.

Process measure monitoring includes optional reporting aspects that allow facilities to systematically report information on *C. difficile* prevention process measures for hand hygiene and gown and gloves use. These measures require direct observation and are described in Sections I.B1a. and I.B1b. (MDRO option - Prevention Process Measures). Personnel other than the IP may be trained to perform these observations and the collection of data elements.

Use NHSN forms to collect all required data, using the definitions of each data field as indicated in the "Instructions for Completion of MDRO/CDAD Forms". When denominator data are available from electronic databases, these sources may be used as long as the counts are not substantially different (+ or – 5%) from manually collected counts.



A. Required Reporting

Option 1. Clostridium difficile Infection Surveillance

<u>Settings:</u> Surveillance will occur in any of 3 types of inpatient locations: (1) intensive care units (ICU), (2) specialty care areas (includes hematology/oncology wards, bone marrow transplant units, inpatient dialysis units, solid organ transplant units, long term acute care areas), and (3) any other inpatient care location in the institution (e.g., surgical wards). Facilities may choose to report facility-wide. Surveillance will <u>not</u> be performed in Neonatal Intensive Care Units (NICU).

<u>Requirements:</u> Surveillance for CDI should be performed in at least one location in the healthcare institution for at least 3 calendar months as indicated in the *Patient Safety Monthly Reporting Plan* (CDC 57.106).

Definitions:

Report all nosocomial infections where *C. difficile* is the associated pathogen. Refer to the CDC Definitions for Nosocomial Infections document for gastroenteritis (GI-GE) or gastrointestinal tract (GI-GIT) infections criteria (http://www.cdc.gov/ncidod/dhqp/pdf/NNIS/NosInfDefinitions.pdf).

Cases of CDI that are not present or incubating at the time of admission (i.e., meets criteria for a healthcare-associated infection) should be reported as gastroenteritis (GI-GE) or gastrointestinal tract (GI-GIT) infections, whichever is appropriate. Report the pathogen as *C. difficile* on the *MDRO or CDAD Infection Event* form (CDC 57.126). (See Instruction Table 2 for completion instructions). If the patient develops both GI-GE and GI-GIT CDI, report only GI-GIT using the date of onset as that of GI-GE CDI. (This corresponds to surveillance for healthcare-onset, healthcare facility-associated (HO-HCFA) CDI in recently published recommendations (McDonald, et al. *Infect Control Hosp Epidemiol* 2007; 28:140-145), which is considered the minimum surveillance for CDI.)

CDAD (or CDI) Complications: CDI in a case patient within 30 days after CDI symptom onset with the following:

- Admission to an intensive care unit for complications associated with CDI (e.g., for shock that requires vasopressor therapy)
- Surgery (e.g., colectomy) for toxic megacolon, perforation, or refractory colitis;
 AND/OR



 Death caused by CDI within 30 days after symptom onset and occurring during the hospital admission.

Numerator and Denominator Data: The numerator data are reported on the MDRO or CDAD Infection Event form (CDC 57.126). (See Instruction Table 2 for completion instructions). The patient day denominator data are reported using the MDRO and CDAD and Outcome Measures Monthly Monitoring form (CDC 57.127). (See Instruction Table 3 for completion instructions.)

C. Difficile Infections:

Numerator: The total number of CDI cases identified during the surveillance month.

Denominator: The total number of patient days during the surveillance month.

<u>Data Analysis:</u> Data are stratified by time (e.g., month, quarter, etc.) and by patient care location.

C. difficile Infection rate = Number of CDI cases / Number of patient days X 10,000

Option 2. Clostridium difficile Laboratory-identified Event

<u>Settings:</u> Surveillance must be performed either Overall facility-wide or in multiple locations, where *C. difficile* testing in the laboratory is performed routinely <u>only on unformed</u> (i.e., conforming to the shape of the container) stool samples. Consider including *C. difficile* positive laboratory assays from all available inpatient locations as well as all available outpatient locations where care is provided to patients post discharge or prior to admission (e.g., emergency departments, outpatient clinics, and physician offices that submit samples to the facility's laboratory.) Surveillance will <u>not</u> be performed in neonatal intensive care units (NICU) or outpatient dialysis centers.

Requirements: Facilities must choose one or more of three reporting choices: (A) report LabID Events for the entire facility, but by each location (Facility-wide by location), requiring separate denominator submissions for each location, (B) report LabID Events for only Selected locations, and (C) Overall facility-wide (with only one denominator for the entire facility) (See protocol Table 1). Facilities must indicate each reporting choice chosen for the calendar month indicated in the *Patient Safety Monthly Reporting Plan* (CDC 57.106). Facilities reporting Overall facility-wide, which allows for the most complete data acquisition, can also report by Selected locations (i.e., (C) and (B)); otherwise, facilities must choose between choice (A) alone, (B) alone, or (C) alone (See protocol Table 1). Surveillance for positive laboratory results must be reported for 3 consecutive months to provide meaningful measures.



Definitions:

CDI-positive laboratory assay:

- A positive result for a laboratory assay for C. difficile toxin A and/or B,
 OR
- A toxin-producing *C. difficile* organism detected in the stool sample by culture or other laboratory means.

Duplicate C. difficile-positive test: Any C. difficile positive laboratory assay from the same patient following a previous C. difficile positive laboratory assay within the past two weeks.

Laboratory-Identified (LabID) Event: All non-duplicate C. difficile positive laboratory assays. (See Figure 2)

Numerator and Denominator Data:

Numerator: Data will be reported using the Laboratory-Identified MDRO or CDAD Event form (CDC 57.128). (See Instruction Table 1 for completion instructions).

Denominator: Patient days, admissions, and encounters (for ER and outpatient locations) are reported using the MDRO and CDAD Prevention Process and Outcome Measures Monthly Monitoring form (CDC 57.127). (See Instruction Table 3 for completion instructions.)

CDI Data Analysis:

Data are stratified by time (e.g., month, quarter, etc.), incident or recurrent, and either aggregated across the entire facility or stratified by patient care location.

Based on data submitted on appropriate forms, LabID Events will be categorized as follows:

- Incident CDI Assay: Any LabID Event from a specimen obtained > 8 weeks after the most recent LabID Event (or with no previous LabID Event documented).
- Recurrent CDI Assay: Any LabID Event from a specimen obtained > 2 weeks and ≤ 8 weeks after the most recent LabID Event for that patient.

All incident or recurrent LabID Events are further categorized by NHSN analytical programs utilizing timing of specimen collection, setting where collected, and previous discharge or future admission.



The following definitions and calculations are built into the analysis capabilities of NHSN. These are some of the main metrics, but additional calculations will be available in NHSN.

Categorization Based on Date Admitted to Facility and Date Specimen Collected:

Community-Onset (CO): LabID Event collected as an outpatient or an inpatient ≤ 3 days after admission to the facility (i.e., days 1, 2, or 3 of admission).

Community-Onset Healthcare Facility-Associated (CO-HCFA): CO LabID Event collected from a patient who was discharged from the facility ≤ 4 weeks prior to date stool specimen collected.

Healthcare Facility-Onset (HO): LabID Event collected > 3 days after admission to the facility (i.e., on or after day 4).

Calculated CDI Prevalence Rates:

Admission Prevalence Rate = Number of non-duplicate CDI LabID Events per patient per month identified ≤ 3 days after admission to the location or facility / Number of patient admissions to the location or facility x 100

Location Percent Admission Prevalence that is Community-Onset = Number of Admission Prevalent LabID Events to a location that are CO / Total number Admission Prevalent LabID Events x 100

Location Percent Admission Prevalence that is Community-Onset Healthcare Facility-Associated = Number of Admission Prevalent LabID Events to a location that are CO-HCFA / Total number Admission Prevalent LabID Events x 100

Location Percent Admission Prevalence that is Healthcare Facility-Onset = Number of Admission Prevalent LabID Events to a location that are HO / Total number of Admission Prevalent LabID Events x 100

Overall Prevalence Rate = Number of non-duplicate CDI LabID Events per patient per month regardless of time spent in location or facility / Number of patient admissions to the location or facility x 100



Calculated CDI Incidence Rates: (see categorization of Incident, HO, and CO-HCFA above). *CDI Incidence Rate* = Number of non-duplicate and Incident CDI LabID Events per patient per month identified > 3 days after admission to the location or facility / Number of patient days for the location or facility x 10,000

Facility CDI Healthcare Facility-Onset Incidence Rate = Number of all Incident HO CDI LabID Events per patient per month / Number of patient days for the facility x 10,000

Facility CDI Combined Incidence Rate = Number of all Incident HO and CO-HCFA CDI LabID Events per patient per month / Number of patient days for the facility x 10,000

B. Optional Reporting

Prevention Process Measures Surveillance (Hand Hygiene and Gown and Gloves Use Only) See Sections I.B1a and I.B1b under the MDRO Option.



Figure 1. MDRO Test Result Algorithm for Laboratory-Identified (LabID) Events

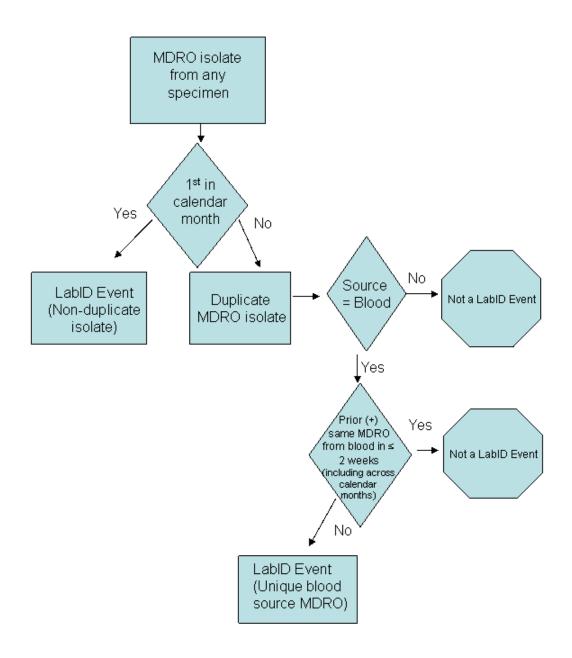




Figure 2. C. difficile Test Result Algorithm for Laboratory-Identified (LabID) Events (+) C. difficile test result Prior (+) in ≤ 2 weeks No Yes Not a LabID LabID Event Duplicate C. difficile test Event



Table 2. Rates and Measures Derived from Various MDRO and CDI Protocol Surveillance Methods

0	F	NIEUTOUS	
Surveillance	Forms	Rate	Measures
Method	N	Determination of the Control of the	D:
MDRO Infection Surveillance	Numerator: 1)Primary Bloodstream Infection	Data are stratified by time (e.g., month, year) and patient care location.	Direct HAI MDRO Incidence Rate
	2) Pneumonia 3) Urinary Tract Infection 4) Surgical Site Infection 5) MDRO Infection Event	MDRO Infection Incidence Rate = Number of infections by MDRO type/ Number of patient days X 1000	
	Denominator: MDRO and CDAD Prevention Process & Outcome Measures Monthly Monitoring		
Laboratory	Numerator:	Admission Prevalence Rate = Number of 1st LabID	Proxy Measures for
Identified Event	Laboratory Identified MDRO or CDI Event	Events per patient per month identified ≤ 3 days after admission to the location or facility / Number of patient admissions to the location or facility x 100	MDRO Exposure Burden
	Denominator:		
	MDRO and CDAD Prevention Process & Outcome Measures Monthly Monitoring	Location Percent Admission Prevalence that is Community-Onset = Number of Admission Prevalent LabID Events to a location that are CO / Total number Admission Prevalent LabID Events x 100	
		Location Percent Admission Prevalence that is Healthcare Facility-Onset = Number of Admission Prevalent LabID Events to a location that are HO / Total number of Admission Prevalent LabID Events x 100	
		Overall Prevalence Rate = Number of 1 st LabID Events per patient per month regardless of time spent in location or facility / Number of patient admissions to the location or facility x 100	
		MDRO Bloodstream Infection Admission Prevalence Rate = Number of all unique blood source LabID Events per patient per month identified ≤ 3 days after admission to the location or facility / Number of patient admissions to the location or facility x 100	Proxy Measures for Bloodstream Infection Admission Prevalence and Incidence
		MDRO Bloodstream Infection Incidence OR Incidence Density Rate = Number of all unique blood source LabID Events per patient per month identified > 3 days after admission to the location or facility / Number of patient admissions to the location or facility x 100 OR Number of patient days for the location or facility x 1,000	
		Overall MDRO Infection/Colonization Incidence Rate = Number of 1 st LabID Events per patient per month among those with no documented prior evidence of previous infection or colonization with this specific organism type and identified > 3 days after admission	Proxy Measures for MDRO Healthcare Acquisition



Surveillance Method	Forms	Rate	Measures
Prevention Process Measures: Hand Hygiene Gown & Gloves Use	Numerator & Denominator: MDRO and CDAD Prevention Process & Outcome Measures Monthly Monitoring	to the location or facility / Number of patient admissions to the location or facility x 100 Overall MDRO Infection/Colonization Incidence Density Rate = Number of 1st LabID Events per patient per month among those with no documented prior evidence of previous infection or colonization with this specific organism type and identified > 3 days after admission to the location or facility / Number of patient days for the location or facility x 1,000 Hand Hygiene Percent Adherence = Number of contacts for which hand hygiene was performed / Number of contacts for which hand hygiene was indicated X 100 Gown & Glove Use Percent Adherence = Number of contacts during which gown and gloves were used /Number of contacts for which gown and gloves were	Direct Adherence Percent: Hand Hygiene Gown & Gloves Use
Active Surveillance Testing (AST) (MRSA & VRE only)		indicated X 100. Admission AST Percent Adherence = Number of patients with admission AST performed / Number of patients admission AST eligible X 100 Discharge/transfer AST Percent Adherence = Number of patients with discharge/transfer AST performed / Number of patients discharge/transfer AST performed / Number of patients discharge/transfer AST eligible X 100.	Admission AST Discharge/Transfer AST
Active Surveillance Testing Outcome Measures (MRSA & VRE Only)	Numerator & Denominator: MDRO and CDAD Prevention Process & Outcome Measures Monthly Monitoring	Eligible patients = All (All patients regardless of history of MDRO) AST Admission Prevalence rate = Number of admission AST or clinical positive / Number of admissions X 100 Eligible patients = NHx (No history) AST Admission Prevalence rate = Number of admission AST or clinical positive + Number of known positive / Number of admissions X 100.	Direct Admission Prevalence Rates of MDRO by AST Eligibility Direct MDRO
		AST Incidence Rate = Number of discharge/transfer AST or clinical positive cases / Number of patient days X 1000	Healthcare Acquisition
CDI Measures	Numerator: CDAD Infection Event or Laboratory-Identified MDRO or CDAD Event Denominator: MDRO and CDAD Prevention Process & Outcome Measures Monthly	<u>C. Difficile Infection rate</u> = Number of <i>C. difficile</i> infections/ Number of patient days X 10,000	Direct HAI CDI Incidence Rate



Surveillance Method	Forms	Rate	Measures
	Monitoring	Admission Prevalence Rate = Number of non-duplicate CDI LabID Events per patient per month identified ≤ 3 days after admission to the location or facility / Number of patient admissions to the location or facility x 100	CDI Prevalence Rates
		Location Percent Admission Prevalence that is Community-Onset = Number of Admission Prevalent LabID Events to a location that are CO / Total number Admission Prevalent LabID Events x 100	Community-onset
		Location Percent Admission Prevalence that is Community-Onset Healthcare Facility-Associated = Number of Admission Prevalent LabID Events to a location that are CO-HCFA / Total number Admission Prevalent LabID Events x 100	Community-onset cases that likely represent intra-facility transmission
		Location Percent Admission Prevalence that is Healthcare Facility-Onset = Number of Admission Prevalent LabID Events to a location that are HO / Total number of Admission Prevalent LabID Events x 100	Healthcare Facility- onset
		Overall Prevalence Rate = Number of non-duplicate CDI LabID Events per patient per month regardless of time spent in location or facility / Number of patient admissions to the location or facility x 100	
		CDI Incidence Rate = Number of non-duplicate and Incident CDI LabID Events per patient per month identified > 3 days after admission to the location or facility / Number of patient days for the location or facility x 10,000	CDI Incidence Rates
		Facility CDI Healthcare Facility-Onset Incidence Rate = Number of all Incident HO CDI LabID Events per patient per month / Number of patient days for the facility x 10,000	
		Facility CDI Combined Incidence Rate = Number of all Incident HO and CO-HCFA CDI LabID Events per patient per month / Number of patient days for the facility x 10,000	